MAR 2 7 2001

Attachment I
510(K) Summary
F1 Diode Laser System

K004021

This 510(K) Summary of safety and effectiveness for the F1 Diode Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Opus Medical, Inc.
Address:	206-3333 Graham Boulevard Montreal, Quebec, Canada
Contact Person:	Dr. Daniel Barolet
Telephone:	514.343.4141
Preparation Date:	11-30-2000
Device Trade Name:	F1 Diode Laser System
Common Name:	Pulsed Diode Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Apex 800 K number K992298
Description of the F1 Diode Laser System	The F1 Diode Laser System delivers a pulsed infrared laser light at a wavelength of 810 nanometers. The laser consists of three interconnected sections: The cabinet which houses the Laser Diode, the power supply, the PC-104, the microcontroller, the umbilical which houses the fiber optics delivery system, the handpiece and the external TE chiller.
Intended use of the F1 Diode Laser System	The F1 Diode Laser System is indicated for use to remove hair in dermatology and plastic surgery procedures.
Performance Data:	Clinical studies were conducted with 17 patients to provide assurance that the performance of the device is equivalent to the predicate device and did not result in any adverse events.
Results of Clinical Study:	Observation in the clinical study were recorded prior to treatment and at 8-10 month after treatment. There were no adverse events in any subject. The study demonstrated that selective photothermolysis targeting melanin in the human hair follicle is an effective tool for hair removal.
Conclusion:	The F1 Diode Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for removal of hair in Dermatology and Plastic Surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Opus Medical, Inc.
c/o Ms. Connie White-Hoy
9630 Towner NE
Albuquerque, New Mexico 87112

Re: K004021
Trade Name: F1 Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: December 15, 2000
Received: December 27, 2000

Dear Ms. White-Hoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: ~~Pending~~ K004021

Device Name: F1 Diode Laser System

Indications for Use:

The F1 Diode Laser System is intended to remove hair in dermatology and plastic surgery procedures.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K004021

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)